through a more reasonable manner, and that is reflected in legislation that has been introduced in Congress by Joanne Emerson, in Missouri, in HR-4301. Her bill would require written certification that the products being offered for sale by an unauthorized distributor were first purchased through an authorized wholesaler.

On question five, we see no easy or practical way in which to implement a pedigree requirement without industry incurring significant costs, and we don't see any advantage by requiring pedigrees since the information that the pedigree would capture is already available or exists as part of the distributor's business records that are subject to inspection by FDA or state board of pharmacy.

Finally, in response to question six, it is FMI's position that written agreements should not be used to determine if a distributor is authorized. Instead, we would hope that FDA would maintain its original interpretation of PDMA in which a distributor is deemed authorized if the entity has an ongoing relationship with the manufacturer through actual sales.

This concludes my statement. I would be happy to respond to any questions that you have, and we appreciate the opportunity to testify.

MS. AXELRAD: Thank you.

MR. TAYLOR: I have a question. You stated during

your presentation that FMI felt that the system has worked well since the passage of PDMA and, therefore, the imposition of the pedigree requirements, you feel, are not necessary. If you have information that helps support that statement, I ask that you submit it to the docket. I think that would be helpful for us to look at.

MR. KELLEY: We can go out to all of our key contact members that are in the pharmacy business and ask that question. I think that what we would get back in terms of feedback is that our members would say that the system is working extremely well right now; that a lot of the core problems that we saw back in the 1980's, which resulted in Congress passing PDMA, have been addressed and the system has been cleansed of the problems that we are all very familiar with from the 1980's in terms of drug samples and illegitimate products finding their way into the distribution system.

MR. TAYLOR: Okay, and that is fair, and that relates to the question that Ms. Axelrad asked earlier, which is obviously there were a set of circumstances in place which led to the passage of PDMA --

MR. KELLEY: Exactly. I would have to add to that that one of the most significant provisions in PDMA was the fact that all wholesalers would have to be licensed and meet various requirements of the FDA, as well as at the state

level. So, everybody is now on a level playing field, if you will, in terms of licensing provisions. That was extremely important in terms of correcting the problems that existed back then.

MR. TAYLOR: Thank you.

MR. O'ROURKE: I am sure you are aware of the potential bill in Congress concerning importation of foreign pharmaceuticals. Do you feel that doing away to pedigree would tend to bring us back to the times of possible counterfeit, adulterated, diverted drugs entering the system, and do we need some form of protection against that?

MR. KELLEY: Well, to answer that I think would be an educated guess on my part, but I would believe, and i would hope, that the re-importation provisions that Congress has just passed would not create a situation that we saw back in the 1980's. I think the system now that is in place in terms of the movement of prescription drugs here, in the United States, as well as with our trading partners in Europe and elsewhere provides a lot of good safeguards that would not allow for counterfeit or adulterated products to come in, or necessitate the need for a pedigree. But I just can't swear on a bible that that is what would happen. It is a little bit out of my bailiwick in terms of re-importation and foreign countries.

MS. O'ROURKE: In other words, would you agree

with earlier statements that the licensing requirements on wholesalers is sufficient to guarantee the storage, handling and record-keeping of prescription drugs and the pedigree is not?

MR. KELLEY: No, I would say that the licensing provisions have put into place what we needed to ensure that consumers are not placed at risk with respect to adulterated, misbranded, expired, subpotent type products, and I don't believe we gain any more by imposing a pedigree on any type of wholesaler that is licensed.

MS. O'ROURKE: Thank you.

MR. TAYLOR: So, it is your view that there is really no necessity for a pedigree at all for anybody, whether they be an authorized distributor or not.

MR. KELLEY: I don't believe that there is. I mean, what we now have is almost twelve years worth of experience since the passage of PDMA and, to my knowledge, the system is working extremely well. I just don't see what additional assurances we would achieve through a pedigree, other than maybe it makes people feel more comfortable but it would be a comfort level that would cost a lot of money.

MS. AXELRAD: My understanding from previous speakers is that in many cases a pedigree is provided, and it is simply that it does not go all the way back to the manufacturer. In transactions between secondary

wholesalers, they do provide a pedigree at least back to the authorized distributor. I think that is what I heard from previous speakers.

MR. KELLEY: And that is done voluntarily, and it is not a requirement at this time, but as some of the previous speakers have mentioned, they would have difficulty getting the pedigrees. So, you would start to see an erosion and a clamping down on the system that currently exists whereby, I would feel, that a lot of companies that are in the business right now would have difficulty getting those pedigrees.

MR. MCCONAGHA: You do represent pharmacies. Is that my understanding?

MR. KELLEY: We do.

MR. MCCONAGHA: So, I will ask a question of you that we asked Miss Winckler earlier. Is it your sense -- does it make a difference to these pharmacists whether or not they are getting drugs with pedigrees today?

MR. KELLEY: Not to my knowledge. I mean, our people routinely buy from secondary wholesalers, as I mentioned. They have established these relationships over the years. They are very comfortable with the companies which they are purchasing the products from. Therefore, we have not heard anybody saying, well, gee whiz, this product did not come with a pedigree; I doubt its authenticity.

That is not what we are hearing out there.

Our members tell us that they want to maintain this option to go out and purchase from secondary wholesalers for the very reasons that I cited, they need the product now, or the product is available at a lower price than they can get it elsewhere.

MS. AXELRAD: I think we ought to correct what might be a misimpression. The pedigree is required. The issue is whether it has to go back all the way to the manufacturer or whether it needs to simply reflect sales from an authorized distributor.

MR. KELLEY: Yes, we are not advocating no pedigree whatsoever. We are worried about the requirements of the pedigree in terms of how we are able, as retail pharmacies and some of our members have distribution centers, of obtaining product from different sources.

MS. AXELRAD: Mr. Ricciardi described a system that they have for making sure that products that they purchase are authentic by buying originally from a manufacturer or an authorized distributor, primary wholesaler, and then keeping on file records of that so that they can compare products that they bring in from secondary wholesalers. Do you know how many, if any, of your members do something like that?

MR. KELLEY: That is an interesting question, and

I never heard that response and I think his company has put a great system in place. I just don't know if our folks do that as well. I just don't know, to be honest.

MS. OGRAM: Do you know whether your people are receiving pedigrees?

MR. KELLEY: That I don't know. I could find out if that is something that would be helpful. Maybe those members of ours who have distribution centers -- they may be receiving them. I really don't know. I could find out and get back.

MS. AXELRAD: I think it would be useful to have sort of broadly, you know, what percentage of sales from your members or purchases from your members are accompanied by a pedigree. We don't need specifics, but generally to get a feel for how many of the purchases have a pedigree and how many don't.

MR. KELLEY: I will try to get that information and we could include it as part of our full statement.

MS. AXELRAD: That would be helpful. Thank you.

MS. O'ROURKE: If possible, deleting whatever you need to delete, if you could perhaps provide a copy of the pedigree that is being used, or an example of something like that.

MR. KELLEY: Okay.

MS. O'ROURKE: Thank you.

MS. AXELRAD: Thank you.

MR. KELLEY: Thank you so much.

MS. AXELRAD: Our next presenter is Alan Goldhammer, representing Pharmaceutical Research and Manufacturers Association.

MR. GOLDHAMMER: Thank you very much for providing us the opportunity to give our perspectives on certain aspects of the PDMA. I am Alan Goldhammer. I handle domestic regulatory affairs at PhRMA, and most of my comments today are going to be on some of the regulatory perspectives, as we see them.

As I think probably everybody knows, we represent the country's leading research-based pharmaceutical and biotechnology companies. Our view is the PDMA is an important piece of consumer legislation that was passed as a result of congressional concern about the integrity of the then existing distribution system for prescription drugs, that it was insufficient to prevent the introduction and eventual resale of substandard, ineffective and counterfeit drugs.

As Miss Axelrad just mentioned, one of the key requirements of the PDMA was the pedigree requirement which was incorporated into the law, requiring identification of prior sales, purchase, trade of such drugs. It is important to note that the oversight committee held eight days of

hearings and issued three reports on the existing distribution system, noting that the integrity of the system was insufficient to prevent the introduction and eventual retail sale of substandard, ineffective or even counterfeit pharmaceuticals. Certainly, one of the key things that the PDMA did was to clean up the trafficking in counterfeit pharmaceuticals at that time.

However, we would also note that as recently as two weeks ago Congressman John Dingell, who was the principal sponsor of the PDMA, took to the floor of the House of Representatives to argue forcefully against the repeal of certain key provisions of this landmark piece of legislation, specifically noting in his floor statement that the PDMA was designed to restore the needed integrity and control over the pharmaceutical market, eliminating actual and potential health and safety problems before injury to the consumer could occur, furthermore stating that he finds nothing today to suggest that the problem with misbranded, adulterated or even counterfeit drugs has been solved and, if anything, the problem may be getting worse. With these cautionary words, it is critical that the provisions of PDMA that require the establishment of a chain of custody or pedigree be preserved.

In terms of compliance with the NDA, PhRMA companies ship finished pharmaceuticals in bulk packages to

licensed drug wholesalers. The wholesaler ensures that the products are stored under the appropriate environmental conditions to prevent product degradation prior shipment to the various pharmacies that dispense directly to the patient. Some pharmaceuticals such as inhalers and nasal sprays are packaged in their unit of use box with accompanying patient directions. Most pills, however, are packaged in large bottles of varying count depending on customer need. For example, a large hospital pharmacy may request bottles of a thousand or greater while a neighborhood pharmacy may request smaller bottles. This practice occurs because the pharmacies want to be able to control their inventories so that product dispensed to the consumer is used within the lot expiration date on the label and there is no overstocking on the shelves.

Not all pharmaceuticals come in pill or tablet form. There are a variety of different formulations -- capsules, freeze-dried powders that have to be reconstituted, transdermal patches and so forth. One of the key features of the PDMA was the requirement to specify minimal storage conditions and handling by distributors so that product integrity is preserved.

The second critical feature of PDMA, and the subject of FDA's final rule published last December, is the requirement for the pedigree from secondary wholesalers that

are not the wholesaler authorized by the pharmaceutical manufacturer. This pedigree regulation is the subject of today's hearing.

The provision establishes a legal chain of custody of the pharmaceutical, assuring that it originated from the manufacturer. The provision serves two purposes. First, it prevents the introduction of counterfeit medications into the supply chain and, second, it provides the necessary information at all levels of the distribution chain so that in the event of a recall the effective pharmaceutical product can be successfully withdrawn from the market. We believe that the final rule promulgated by FDA is an accurate reflection of congressional intent.

In the notice announcing today's hearing, FDA posed a series of questions for people that were interested and associations interested in testifying. We do not have first-hand knowledge of the magnitude of the secondary or unauthorized wholesaler distribution system within the United States. Because of this, PhRMA is not in a position to respond to several of the questions. However, we do offer answers to two of the questions.

Question three, if an act amended by Congress to delete the requirements for provision for the drug pedigree by unauthorized distributors, would there be an increased risk of distribution of counterfeit, expired, adulterated,

misbranded or otherwise unsuitable drugs to consumers and patients?

The answer to this, in our view, is an unequivocal yes. Without a legally required document assuring traceability back to the original manufacturer, there is no guarantee that the pharmaceutical product is not counterfeit. Furthermore, even in cases where the drug product may have originated in an NDA approved manufacturer, there would be no history of where a particular lot of the pharmaceutical was stored. Exacting storage conditions, identified in the NDA, must be maintained to ensure product quality. Thus, American consumers would be placed at the risk of receiving pharmaceuticals that are substandard, or even have no activity, or are adulterated by dangerous by products or contaminants toxic to patients' health.

It is important to consider what types of information the FDA is requesting in the pedigree. This can be found in the final rule at section 203.50(a)(1) through (7). Such information includes the name of the drug, dosage, container size, lot or control number, name of the business selling the drug, and the date of the transaction. All of this information is readily available in the transaction order between the pharmaceutical manufacturer and the authorized wholesaler.

The second question that we wish to comment on is

question six, if actual sales by a manufacturer or a distributor were used by the FDA as the only criterion to determine whether an ongoing relationship exists between them and, as a result, whether the distributor is an authorized distributor of record, would it result in more distributors being authorized than if a written authorization agreement is required? What other types of criteria could be used by FDA to determine who these authorized distributors are?

PhRMA believes it would be wrong for FDA to use simple sales records as the only criterion for an authorized distributor. This clearly goes against congressional intent as outlined in section 503(e)(4)(a), which states the term authorized distributors of record means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's product. A small number of sales to a secondary distributor does not meet the statutory definition, in our view. Companies establish specific business relationships with wholesaler distributors for a wide variety of reasons. The definition of authorized distributors of record in the final regulations recognized these relationships as a clear, reasonable, enforceable way and, thereby, implements Congress' intent in the PDMA, and we believe the definition should be retained.

In conclusion, we believe that the issue cannot be addressed adequately without recognizing the extensive congressional hearing record that led to the passage of the specific provisions of the PDMA, subject of today's meeting. We are concerned that the situation of wider availability of misbranded drugs, or drugs that are subpotent not be allowed to recur, and we urge the FDA to continue to adhere to the congressional safeguards established in the PDMA, which are faithfully incorporated into the final PDMA rule.

I will be pleased to entertain probably a number of questions since I think we are the only people from the manufacturing side here today.

MS. AXELRAD: Since I am the presiding officer, I am going to take the opportunity to go first. We were told this morning that Congressman Dingell was a co-sponsor of HR-4301. What is PhRMA's position on that legislation?

MR. GOLDHAMMER? We have not taken a position on the legislation.

MS. OGRAM: We have heard from a number of speakers this morning that manufacturers commonly refuse to provide the written authorization agreement. Can you give us some idea of how often this does occur and what the reasons are if a manufacturer is engaged in selling to a distributor or a wholesaler?

MR. GOLDHAMMER: We have not discussed that with

our membership. We look at that, as well as a number of other tangential issues that were discussed this morning, as falling into the marketing domain and, as you might imagine, we have been very cautious over the last five years of discussing specific marketing issues within the trade association and have disbanded our marketing committee, I think, at that time because it does clearly raise potential antitrust issues.

MS. O'ROURKE: You have mentioned yourself that the pedigree is intended to go back to the manufacturer. So, that raises the issue, since testimony indicates today, that there is literally a web of transactions among and between authorized and unauthorized and manufacturers of transfer or prescription drugs. So, if a pedigree is either not required or required to be passed on by an authorized distributor, how can this be achieved?

MR. GOLDHAMMER: I think addressing your point of the secondary market, which I just heard for the first time today and I think I appreciate now perhaps better the interchange of our goods in commerce as they flow from authorized distributors to pharmacies and then to secondary distributors, and secondary distributors actually get their product to pharmacies as well -- it actually does appear to be quite complex. I think our perspective on this, and one of the issues that I have been working on at PhRMA for the

last year in terms of the safe use of pharmaceuticals and improving product safety, again, having the pedigree does help assure that safety because it ultimately does go back to the manufacturer. It is traceable back to the manufacturer. Certainly, also in the case of a recall it does provide another added benefit to making sure all of the product does get off the shelves of the pharmacists before a product finds its way into the hands of a patient. So, it is an extra margin of safety from that perspective.

MS. O'ROURKE: I understand it is an extra margin of safety, which is why I am concerned that if there is no requirement for authorized distributors to pass along a pedigree basically that margin of safety could be mitigated considerably, if that is not a requirement, and testimony earlier has indicated this would be a big burden to the authorized distributors or perhaps the manufacturers, that the traceability or record-keeping requirements are too onerous. Can you comment on that?

MR. GOLDHAMMER: Well, certainly in the case of the data elements that make up the pedigree, those are all available at the point of the first transaction, whether it be to the authorized distributor or to the secondary and unauthorized distributor. When we talked to our members, we specifically asked them are these seven data elements present in your transaction, the purchase order transaction

that goes on? And, we were assured that, yes, they were. So, in the case of a secondary unauthorized wholesaler that original record, to our mind, would fulfill the requirements of the FDA pedigree.

Now, it begs the question, and we are not prepared to answer that question -- I really think you need to go back and talk to the earlier speakers and we would hope the NWDA would weigh in on this topic as well, as to what the burden is in terms of keeping additional paperwork because there is no question that if you are looking at a product that is going through ten transactions, I would assume that is ten separate documents that needed to be provided as part of the pedigree.

MS. AXELRAD: Alan, in your statement you talked about how important and what an impact there would be in terms of public health if we changed the regulations. I guess we have been hearing that for the last twelve years they have been operating under an entirely different system, and I don't think anybody that we have heard today has indicated that there has been a major problem associated with the system as it has stood today, where the pedigree has not been provided going all the way back to the manufacturer.

MR. GOLDHAMMER: No, I think that some of the things that PDMA was set up to do, for instance controlling

re-importation, really solved a fundamental problem, and that was large amounts of counterfeit products getting into this country. There still is a fair amount of that going on. I don't have the numbers off the top of my head, but if you look at the customs numbers about drug seizures at the border of counterfeit products that have tried to enter the country, it has risen a significant fold over the last five years. We have not done a complete analysis of the Jeffords Amendment recently passed, but we are envisioning that the pedigree requirement could be even more important next year, as FDA goes through and tries to develop regulations implementing Jeffords because now you have two distribution channels. You have the domestic distribution channel which we are all familiar with and even the secondary wholesalers are an established part of, and now you are going to have the second distribution channel of bringing in imported products which are not coming from the manufacturer. They are coming from another source beside the manufacturer, and presumably the pedigree then would originate -- I would presume -- at the importer. Then, if that product is entering commerce you have two different sets of products, which could raise totally different safety issues.

MR. MCCONAGHA: So, would you support then a requirement for pedigrees for everybody, primary and secondary wholesalers?

MR. GOLDHAMMER: As I said in our statement, the data elements for the pedigree are in the original bill of sales from the pharmaceutical company whether it goes to an authorized or an unauthorized wholesaler. So, from our perspective, the data is there.

MR. MCCONAGHA: Well, let me ask the question more directly. You are in support of the pedigree requirement, that it seems to perform a certain public health function.

MR. GOLDHAMMER: Yes.

MR. MCCONAGHA: Is there any reason to believe that that is diminished if you requirement the same of a primary wholesaler? I mean, using the public health rationale, why wouldn't we require it of a primary wholesaler just as well as the secondary?

MR. GOLDHAMMER: I think the thinking behind that was -- again, I think it would be useful to look at some of these transactions that are occurring -- I think the thinking was as the drug goes to the primary wholesaler, then goes out but doesn't come back in, if we what heard today, the drug is actually coming back in and then going out again, then the answer would be, in my mind, yes, the pedigree would serve a useful purpose because you no longer have this one-way flow of pharmaceuticals from wholesaler to wholesaler to patients but, rather, as we have heard, it is going all around the place. It is maze-like, going around

to different distributors.

MR. MCCONAGHA: I have a related question, if I may. If you were to require pedigrees of everybody it would seem to necessarily implicate the significance of having an authorized distributor requirement. When you made your remarks earlier you mentioned that the status quo in terms of a definition of an authorized distributor, for whatever reason, didn't seem to carry the day. You supported the idea that there should be this explicit written contract. Could you just elaborate on that? What is the concern about an authorized distributor relationship as is kind of currently practiced?

MR. GOLDHAMMER: Again, that is not something that we have discussed with the membership. I would be glad to bring that question back and find out. I would suspect there are a variety of business reasons that they elect to choose one distributor over another. It may be economic. There may be some legal issues that I am unaware of.

MR. MCCONAGHA: I think we would much appreciate that, if you could just submit that to the docket.

MR. GOLDHAMMER: Yes, we will be glad to do that.

MS. JACOBS: I have a question. You stated that you believe that the final rule is an accurate reflection of congressional intent, and I am asking whether PhRMA means that statement to apply to blood-derived products and, in

particular, the question of whether or not blood centers can be healthcare entities and be excluded from being wholesalers for blood-derived products?

MR. GOLDHAMMER: That is an easy question to answer because PhRMA got out of the blood product business I believe about ten years ago. So, we do not even have a section within the organization that deals with those products right now.

MS. JACOBS: So you are not commenting right now?

MR. GOLDHAMMER: Right, we are not commenting on those questions.

MS. AXELRAD: Alan, can you comment on whether you think that if the rule went into effect as it is written, and now that you have sort of heard from everybody about what a complex drug distribution system there actually is, what effect it might have and what might be the consequences if that system were disrupted, as we have heard today, and that many of the secondary wholesalers would be forced to go out of business?

MR. GOLDHAMMER: Well, I think that the one issue that we heard that clearly is of considerable concern, and we have been looking at this since FDA raised these PDMA questions with us about eight or nine months ago, is the ability of patients to have access to needed pharmaceuticals. We have certainly internally discussed the

problems of a small drugstore in a rural area that, for whatever reason, one of the "big five" distributors doesn't wish to service because it is not economically viable and, yet, there are a number of smaller wholesalers that do this. Patients need our products, and we want to ensure that they get those products and if there are impediments to that as a result of a regulation or distribution issues, we would really like to hear that. I think we clearly heard some messages today that we will go back and discuss internally and see if perhaps there is a better way of working around some of these issues, but our first and paramount interest is making sure the patients have access to the medicines.

DR. TAYLOR: Alan, to manufacturers sell to unauthorized distributors and, if so, under what circumstances?

MR. GOLDHAMMER: Again, that gets into the marketing area and I can tell you for a fact that over the last five years we have not asked that question. I will be glad to go back to our general counsel and see if that is a question we can ask of the membership.

MR. TAYLOR: Okay, I would appreciate it.

MR. GOLDHAMMER: Okay.

MS. AXELRAD: Can you comment -- I don't know, this may go to the same thing you just sort of didn't answer, on the marketing aspects, but I am interested in can

you at least confirm factually whether pharmaceutical manufacturers do offer pharmaceuticals at different prices across the country, that this whole system of arbitrage that we heard described is dependent upon the different pricing practices?

MR. GOLDHAMMER: That is also an easy question to answer. No, we don't. That would probably be very forbidden territory. We are already under a subpoena for average wholesale price issues.

MS. AXELRAD: Okay, so you are saying that you can't answer these questions because of antitrust concerns?

MR. GOLDHAMMER: Yes. We have taken a very hard line on any discussions about sales and pricing. I think if there is a way of addressing John's question in terms of getting some qualitative data, percentage of selling to a secondary wholesaler versus authorized wholesaler, that may be something that we can do.

MR. TAYLOR: Fair enough.

MS. AXELRAD: Thank you. Our next speaker is Dr. Charles Franz, from the American Veterinary Distributors Association.

DR. FRANZ: Good morning. Thank you for allowing me time this morning to testify on a regulation that, I believe, without modification will cripple the supply of prescription drugs in our nation. I will address issues

that affect the animal health aspects of the regulation.

I speak today on this issue from three perspectives: one, as a veterinarian concerned about the availability and cost of medications to treat companion animals; two, as an employee of NLS Animal Health, a veterinary distributor based in Maryland, servicing veterinarians in about seventy-five percent of the country; and, three, as president of the American Veterinary Distributors Association, a trade association of animal health companies representing the vast majority of those in our industry.

With extensive industry consolidation in the past decade and the decrease in the number of distributors to which pharmaceutical manufacturers sell their products, available sources from which veterinarians may purchase drugs have diminished. The need for secondary wholesalers of pharmaceuticals continues to increase. Veterinarians must have human labeled drugs readily available since, in many cases, there is no FDA-approved veterinary labeled drug to treat numerous companion animal illnesses.

Veterinary distributors fill this need by providing human label drugs to veterinarians. These drugs are primarily purchased from various human pharmaceutical distributors. Some are authorized distributors and some are not. To require the distributor to pass pedigree

information on to the veterinarian would prohibit veterinary distributors from supplying most of these products. The veterinarians, their clients and the animal patients would all suffer. In a society that demands, expects and deserves cutting-edge care for its 110 million dogs and cats, it is essential that these products remain readily available.

If veterinary distributors were no longer able to carry these products, larger authorized distributors and drug manufacturers would not be able, nor would they want, to carry the cost of servicing 22,000 U.S. veterinary hospitals. Secondary wholesalers are essential in the efficient distribution of these pharmaceuticals.

To eliminate or curtail these secondary wholesalers would not only reduce price competition, but also reduce the ability of the drug distribution system to effectively move products to the areas in need. The pedigree information would be impossible to provide since a distribution's source of many of these products would not be required to provide the pedigree.

More importantly, this burdensome paperwork is unnecessary to assure the safety of the drugs within the supply chain. Existing regulations already require that complete records of receipt, distribution and other disposition be retained by wholesaler distributors and be available for inspection by FDA state authorities or law

enforcement.

Questions have surface asking whether deleting the pedigree requirement would cause an increased risk of distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable drugs. The language proposed in HR-4301, as we have discussed this morning, provides additional safeguards in the form of written certification from an unauthorized distributor that the drugs were first purchased by an authorized distributor. This certification would be provided by unauthorized distributors to customers and would be subject to strict criminal penalty if falsified. This bill maintains the integrity and standards created by the PDMA without the burdensome, impractical pedigree requirement. There is no increase in risk to the consumer by allowing this more practical solution to replace the pedigree.

With the suggestion that authorized distributors be required to provide pedigree information, substantial additional cost would ultimately be passed on to the consumer. As the current election process winds to a close next week, we are all aware of the extensive dialog this year concerning the cost and availability of drugs to consumers and patients. Do we want to place unnecessary burdens on distributors that can only increase those costs and provide no real benefit to the public? The veterinary

distribution industry already operates under extremely low margins. There is no room for any absorption of increased costs. These costs likely would be passed entirely on to the consumer.

In the veterinary side of this business, it is essential that distributors be recognized as authorized strictly based on the presence of sales between the manufacturer and distributor. Very few relationships between these two parties are consummated by a written agreement. To require written agreements as evidence of an authorized distributor relationship would further drive distributors veterinary distributors out of business. This would certainly result in higher prices and decreased availability of drugs to the consumer. The PDMA is plain in defining an authorized distributor as one that has an ongoing business relationship. There is no need for FDA to change this interpretation.

The issues surrounding the assurance of a good supply of safe and effective drugs in the marketplace, whether for humans or animals, is of utmost concern to all. Our industry must work with the regulatory authorities to ensure that this is the case. However, the final rule on PDMA, as published in the Federal Register on December 3rd, 1999, places unnecessary burdens on the pharmaceutical industry. There is no possible good to come from severely

limiting competition in this industry. We must continue to improve the supply of safe, effective drugs available to the consumer. These drugs must be available from multiple sources if we are to have the price competition that is so important to our economic system.

I believe adoption of language similar to that proposed in HR-4301 will provide sufficient safeguards to assure safety in pharmaceuticals while ensuring the availability of the drugs that consumers need to maintain health and viability for themselves and their pets. Your consideration in revising the final rule on the PDMA is strongly urged and sincerely appreciated. Any questions?

MS. AXELRAD: Thank you.

MR. TAYLOR: I have one question, and I think you have made this fairly clear in your talk but I just want to make sure because I don't have as much grounding in the vet medicine program, but it seems to me that you agree with the concerns that were echoed in the earlier panel. Essentially, even though your distributors are focused on veterinary products, all the same concerns apply for the most part across the board.

DR. FRANZ: The truly veterinary labeled products that we purchase are purchased directly from the manufacturer of those products, but there are a lot of human pharmaceuticals used in the veterinary industry to treat a

wide array of conditions that it would never be feasible for a company to apply for approval and spend the money required to get a drug approved to treat cats, or whatever.

MR. TAYLOR: Thank you.

MS. AXELRAD: We don't have anyone on the panel from the Center for Veterinary Medicine, but we have made them aware of your comments, and we will be involving them, because of the issues that you have raised associated with your industry, in our discussions on what we will do as a result of this.

DR. FRANZ: We have a very good working relationship with CVM and look forward to working with them on this.

MR. TAYLOR: And they noted that you would echo many of the concerns that we would hear from the human drug side.

DR. FRANZ: Correct.

MS. AXELRAD: Thank you.

DR. FRANZ: Thank you.

MS. AXELRAD: Our next speaker is Dr. Larry Sasich, Public Citizen Health Research Group.

DR. SASICH: Thank you very much. Public Citizens Health Research Group appreciates this opportunity to comment on the very important consumer protection aspects of the final rule implementing Prescription Drug Marketing Act

of 1987. This law contains provisions intended to prevent the wholesaler distribution and sale of subpotent, adulterated, counterfeit or misbranded prescription drugs and bulk substances to the American public by requiring certain wholesalers and unauthorized distributors, as opposed to authorized distributors, to produce a paper trail or pedigree documenting all prior sale, purchase or trade of a drug starting with the manufacturer.

Unfortunately, Congress seriously erred in not mandating that all distributors, both unauthorized and authorized, be required to maintain such a pedigree for the drugs and bulk drug substances that they sell. This has left the door open for unscrupulous distributors, even authorized ones, to launder counterfeit or substandard drugs that could be dispensed to an unsuspecting public.

The unequivocal resolution to this potentially hazardous loophole in the law, in order to preserve Congress' intent and insure a prescription drug supply free of substandard, ineffective or counterfeit drugs, is a legislative fix that requires all distributors to maintain a pedigree for the drugs that they sell. Any suggestion that PDMA should only be adjusted by altering the definition of an authorized distributor or that an unauthorized distributor need only certify that drugs they sell originated with the manufacturer or authorized wholesaler

only increases the number of distributors that could possibly launder substandard or counterfeit drugs. Such suggestions are, therefore, dangerous and irresponsible.

In drafting PDMA in 1987, Congress found, in part, that -- and these are exact quotes that I wanted to read; I found them unusually strong and pointed, number one, American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.

Two, the integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective or even counterfeit drugs.

Three, the existence and operation of a wholesale submarket, commonly known as a diversion market, prevents effective control or even routine knowledge of the true sources of prescription drugs in a significant number of cases.

Four, large amounts of drugs are being re-imported to the United States as American goods returned. Five, the bulk resale below wholesale priced prescription drugs by healthcare entities for ultimate sale at retail helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

Congress was provoked and acted responsibly,

except for the authorized distributor omission mentioned above, in drafting and passing PDMA after several cases of drug counterfeiting were uncovered in the mid-1980's. One of these cases involved the importation and distribution of sixteen lots, comprising over one million tablets of counterfeit Ovulin-21, an oral contraceptive, in 1984. The counterfeit pills were found to be subpotent and two pregnancies were known to have occurred in women who used these pills.

In our opinion, as the cost Americans pay for prescription drugs continue to skyrocket, and as the disparity in these prices continues to grow in comparison to other countries, the economic incentives for counterfeiting and selling substandard drugs increases proportionately. This incentive is now greater than ever before.

We fully support the FDA's interpretation of PDMA that a person importing a prescription bulk drug substance into the United States, intended for pharmacy compounding, is engaged in wholesaler distribution and must provide a pedigree showing all prior sales and purchases of the prescription drug substance. Arguments by trade groups representing that nefarious pharmacy compounding industry that bulk drug substances were not intended by Congress to be covered by PDMA are without serious merit. Their argument that a pedigree requirement for distributors of

bulk drug substances will negatively impact the public's health by limiting supply of these drugs from potentially unknown sources is ludicrous. Undoubtedly, there will be increased costs and logistical problems for distributors in meeting PDMA's pedigree requirements. In the long-term increased costs are always paid by consumers.

Logistical problems in tracking the pedigree of drugs is not a legitimate reason for not requiring all distributors to maintain a pedigree. In 1996, 12.7 million units of blood were donated in the United States, and each of these units can be processed into as many as four products. Since the early 1990's blood banks have been required to track all products produced from a unit of blood and to be able to track each product back to the donor of the original unit of blood. In 1999 this amounted to keeping track of 23 million be products. Substandard blood and drugs, both, can have negative safety consequences for the public. If it is possible to maintain a pedigree for every blood product in distribution, it is also possible to do so for drugs.

In closing, as we were preparing our comments we thought back to a number of polls over the last several years that we have received from consumers about the FDA recall notices for manufacturing defects that we published in one of our newsletters. It is not infrequent that we get

complaints from consumers when they go to their pharmacy and their pharmacist cannot tell them whether or not, in fact, they were dispensed a drug that was recalled. So, this is something that we would just like to throw out for consideration, and that is a possible additional benefit to the public if PDMA is legislatively amended to require all wholesale distributors of prescription drugs to maintain a pedigree. A pedigree requirement could be the basis for a more effective system of notification of pharmacies and patients of a drug recall. Now, for example, if a manufacturer or the FDA issues a drug recall on one or more lots of a prescription drug a pharmacy will remove the implicated lots from its shelves. However, a pharmacy has no way of knowing if it may have dispensed recall lots of a drug if the recall was issued after the pharmacy had dispensed all of its stock of the implicated drug. By having access to the pedigree information through a wholesaler, a pharmacy could verify if it did, in fact, dispense a subsequently recalled drug and notify the patients who had received that drug.

In closing, Public Citizen urges the FDA work with Congress to close the serious loophole that now exists in the Prescription Drug Marketing Act of 1987. Thank you very much for the time and your attention.

MS. AXELRAD: Thank you.

MR. MCCONAGHA: We have heard earlier speakers suggested at least that there are other mechanisms at play, be the sales records, other regulations that dealt with the handling of prescription drugs, this seemed to go some distance toward supplying the protections that a pedigree might also provide. Do you have any response to that suggestion?

DR. SASICH: Well, I know what you are talking about, and as I was listening to some of the previous speakers it sounds like all of the data were there; they just need to be rearranged in a way that is rapidly useful. I think being able to access pedigree records or the types of records that we were talking about is very important. If it is a class I or a class II recall, for instance, the system should be able to respond very rapidly at the level of the patient. I don't know if that answers your question directly but it seems all the information is there, and that with the present technology that we have available that it would be possible to organize that information in such a way that actually serves as a pedigree, and we believe that the pedigree requirement is a very important public safety protection.

I think safety is an abstraction and things should be done to try and prevent errors. I think it is very, very poor public policy, and certainly public health policy to

have to wait until you find a pile of bodies before you take action. Science has taught us over the years, and we have experience, that when subpotent, untested products get into the distribution system people get hurt. It happened maybe fifty or sixty years ago in some cases, but it did happen and there is no sense that we should have to relive those kinds of experiences before some preventive action is taken or improved.

MR. MCCONAGHA: Just to follow up on that, we heard from an earlier speaker that it was at least his view to some extent that the gains we have made under the current system were, in large part, due to other PDMA provisions. In particular, he cited the state licensing requirement. Do you have a response to that? Is it your view that it is, in fact, the pedigree that makes a difference here?

DR. SASICH: I think potentially that it could because, you know, either certifying or state licensing requirement -- pharmacists, physicians, and a whole lot of other people who have licensing requirements do an awful lot of bad things and just by having a license doesn't mean that that particular entity is a perfect agent for the public safety. When it comes to products that potentially impact the public's health, I think strong regulatory oversight is absolutely mandatory, and I think that the requirement of a pedigree would give FDA field officers the opportunity to

make sure that as drug products move through the distribution system that they were handled properly and according to their NDA.

MR. MCCONAGHA: Thank you.

MR. TAYLOR: Larry, during your oral testimony and in your written that you submitted, you talk about how the pedigree requirement could be a useful tool in ensuring effective notification in the context of recalls. Any information, any further information that you have developed, you know, please submit to us. You have given one example of how, from a practical standpoint, it would serve or benefit but if there is any work beyond that -- I think you alluded to the fact that you had received some feedback from consumers.

DR. SASICH: Yes, from consumers and I have been calling some pharmacists lately. This popped up I guess most recently when there were a large number of recalls of Dilantin for dissolution problems; also for some Synthroid and L-thyroxine recalls when pharmacists couldn't tell consumers whether or not they had actually been dispensed a lot of the product that had been recalled. It is very, very upsetting and I think that we are technologically sophisticated enough that we should be able to tell a patient whether or not they were dispensed a drug that was recalled, and we should be able to replace that very, very

rapidly.

MR. TAYLOR: Thank you.

MS. AXELRAD: Larry, we have heard a lot about how the secondary wholesalers are being put out of business, and that there would be disruptions in supply to consumers of these drugs if the rule goes into effect as it was published. What is your position on that?

DR. SASICH: Well, you know, every time some aspect of more stringent regulations or requirements are brought up that could potentially affect the public's health, those that are regulated, it seems, consistently try to blackmail the public. You won't have your drugs if you regulate us and if you make us do A, B, C or D, and that is something that I am just not willing to buy. We have heard those stories for years and years in a number of situations. Perhaps it started back in 1962 when the pharmaceutical industry said if we are required to show that drugs are effective, then there won't be anymore drugs; there won't be anymore research; drugs will be too expensive to market and no one will be able to afford them. If there is a profit to be made somebody will fill any voids that might happen in the marketplace very quickly. I am confident of that.

MS. AXELRAD: We also heard this morning that even if that were the case and people were to step in, there would be far fewer in the marketplace and as a result prices

would rise.

DR. SASICH: Well, one of the first lessons of economics 101 is that any free market system eventually evolves to an oligopoly where there are only one or two major players. This is what you would exactly expect in a free market. So, I don't know why it should come as such a surprise that we might have fewer wholesalers in the future. That is what happens in a free market system.

MS. O'ROURKE: Do you think it would make any difference, help, hinder or not count at all whether a pedigree was a standardized form, perhaps a government form?

DR. SASICH: Well, you know, those types of details I think should be left up to the regulatory authority because my understanding is it would be FDA's field office that would be looking at these records, and I suppose if I was an inspector I would want to look at a standardized form so I didn't have to look at different ones from all around the country. I mean, there seems to be a relatively small number of data elements that are actually asked for in the law.

MR. O'ROURKE: Thank you.

MS. AXELRAD: Thank you very much.

DR. SASICH: Thanks.

MS. AXELRAD: We will adjourn now for lunch until 1:15 and return here for the rest of the session. Thanks.

[Whereupon, at 12:15 p.m., the proceedings were recessed for lunch, to be reconvened at 1:20 p.m.]

AFTERNOON SESSION

MS. AXELRAD: For the schedule and logistics this afternoon, we have five scheduled speakers. We have one person from the audience who has indicated an interest in making some remarks, and I have asked Mr. Young if he would be willing to come up and answer a few more questions that have occurred to us as a result of hearing the presentations from some of the other speakers, and he has agreed to do that. So, we will do it in that order, the scheduled speakers, and then the person from the audience, and then we will have Mr. Young answer a couple more questions.

Our next speaker on the agenda is Shelley Capps, representing the International Academy of Compounding Pharmacists.

MS. CAPPS: Thank you. My name is Shelley Capps and I am the Executive Director of the International Academy of Compounding Pharmacists. Accompanying me is Mary Kate Whelan, general counsel.

I appreciate this opportunity to speak before the FDA on behalf of compounding pharmacists and patients who benefit from compounded medications. The International Academy of Compounding Pharmacists represents the interest of more than 1,400 compounding pharmacists. We are very concerned that FDA's December 3rd, 1999 final rule, if implemented as written, will have a devastating impact on

the ability of compounding pharmacists to obtain bulk drug ingredients necessary to fill prescriptions for compounded medications. The lack of supply of drug ingredients will seriously affect the well being of the tens of thousands of patients who requirement custom-tailored medical therapies, treatments that cannot be obtained otherwise.

There are two critical points that I would like to make today. First, the FDA's new requirements impose an unnecessary and unreasonable burden on wholesale distributors and compounding pharmacists without furthering Congress' intent of safeguarding the public. Congress' objectives can be met through monitoring and enforcement of the existing regulatory safeguards without the burden of repetitive record-keeping and tracking which will not protect the public but will increase costs to distributors, pharmacies and ultimately to consumers.

My second point is that Congress did not intend that the requirements set forth in FDA's final rule apply to bulk drug or chemical ingredients. The pharmaceutical industry began with the compounding of drugs and treatments by individual physicians and pharmacists. During the past century manufacturers have made giant leaps forward in developing new treatments for innumerable patient ailments. However, despite the many technological advances in the pharmaceutical industry, compounding remains a vital element

of quality patient care. Compounding fills the gap in treatment left by mass produced drug and chain drug stores.

The importance of compounded drug therapies to patient health is well documented. Each of us, as individual patients, reacts to medicines differently depending upon our physical makeup. Some people, through allergies or other sensitivities, simply cannot tolerate standard drug formulations. Some patients need drugs that manufacturers have discontinued for economic reasons. Compounding allows physicians and pharmacists working together to provide custom-tailored medications that are not commercially available to meet individual patient needs.

For example, if a patient is allergic to a preservative or a dye in a manufactured product, the compounding pharmacist can prepare a dye-free or preservative-free dosage form. Children often refuse to take medications because of taste. Compounding pharmacists can introduce flavor ingredients to such drugs as antibiotics or anti-seizure medications to make these necessary medical treatments palatable for children. Likewise, children and other patients like hospice patients who have difficulty swallowing a capsule can, instead, be prescribed a compounded lozenge, lollipop, suppository or topical gel.

Compounding is also important in preparing medical

treatments that require individualized dosage strengths and product formulation. For example, compounded treatments are often used to prepare safe and effective hormone replacement therapies for women through the ability to alter strengths and product formulations, pills, topical gels or patches for individual women's physical requirements. Drug companies do not, and cannot, provide this type of patient-specific individualized drug therapy.

Congress has recognized the important health benefits of compounded therapies, as demonstrated most recently by the passage of the 1997 Food and Drug Administration Modernization Act, FDAMA. FDAMA formally recognized the benefits that compounded medications play in treating the unique medical needs of patients. Through this legislation Congress specifically acknowledged that pharmacists will need to use bulk drug ingredients in compounding. Without bulk drugs most compounding is not possible.

FDA's final rule will implement provisions of the Prescription Drugs Marketing Act of 1987. Congress passed PDMA for two principal reasons, to protect American consumers from mislabeled, adulterated or counterfeit prescription drugs and, secondly, to protect fair competition in the pharmaceutical industry. To prevent the distribution of damaged prescription drugs, Congress created

a drug pedigree requirement. Those wholesale distributors of prescription drugs who are not deemed to be authorized distributors must provide a statement which details the distribution history or pedigree of the drug. An authorized distributor is defined as a distributor with whom a manufacturer has established an ongoing relationship.

For the past twelve years the pharmaceutical industry has relied on an FDA guidance letter which interprets the PDMA pedigree provision as follows: An ongoing relationship can be established by demonstrating two transactions in any 24-month period to be evidence of a continuing relationship, and that an authorized distributor only has to trace the pedigree back to the last authorized distributor, not all the way back to the original manufacturer.

This guidance has served the public well. Over the past twelve years there has been no evidence of an increase in diversion of prescription drugs stemming from industry's following this guidance letter. Further, there has been no intervention by Congress to change the direction of this guidance letter, nor any indication from Congress that the current practice does not serve the public interest.

FDA now seeks to depart from twelve successful years of agency and industry practice by altering these two

interpretations of PDMA. The pedigree provision requires a written agreement between a manufacturer and a distributor to establish an authorized distributor and to require that an unauthorized distributor obtain a drug pedigree which traces the drug all the way back to the original manufacturer. FDA's new requirements will create insurmountable administrative burdens for many wholesalers and particularly for those small wholesale distributors. FDA's final rule does not require authorized distributors to provide pedigree information to unauthorized wholesaler distributors. This places small secondary wholesaler distributors at distinct economic and competitive disadvantages by having to construct a pedigree of a drug back to the original manufacturer, which in many cases may not be possible.

Under FDA's rule an authorized distributor who chooses not to furnish this information can effectively put the secondary distributors out of business. The small wholesaler distributors of bulk drug substances are left entirely at the mercy of manufacturers and major wholesalers. While the large manufacturers and wholesalers will engage in occasional transactions with small distributors for small amounts of selected problems, sufficient to satisfy FDA's present criteria for establishing an ongoing relationship, those same companies

are not likely to take on additional paperwork, disclosure requirements and regulatory burden imposed in separate written agreements or mandated for numerous products and numerous customers.

The FDA final rule will allow large-scale distributors to cherry pick which small distributors get to be authorized distributors. Allowing the large manufacturers to have a competitive advantage will not further Congress' goal of preventing the sale of damaged prescription drugs to American consumers. Rather, it will thwart Congress' intent in leveling the competitive playing field for drug companies. Further, the final rule will disrupt the already complex balance which exists between the large drug manufacturers and the small wholesale distributors and pharmacies. This can only adversely affect the supply of bulk drugs to such small operations and to compounding pharmacists.

Given the intense public concern over the cost of drugs, it is inexplicable why FDA would now initiate this anti-competitive, cost-increasing measure. Indeed, FDA appears to have done no meaningful analysis of the economic impact of this rule or assess its impact on small business. FDA's application of PDMA's pedigree requirements to the wholesale distribution of bulk drug ingredients, and FDA's requirement of a written agreement to demonstrate an ongoing

relationship between distributors will greatly restrict pharmacists' access to bulk drug ingredients used to compound individualized medications.

The Small Business Administration's Office of Advocacy, in its comment to the rule, has pointed out that the implementation of FDA's final rule will adversely affect approximately 4,000 small wholesale distributors of bulk drug ingredients. The vast majority of bulk drug ingredients purchased by pharmacies comes from small repackagers who, in turn, purchase the bulk drugs from small distributors. Because of these relatively small purchases, many wholesalers are unlikely to be listed as authorized distributors. This will trigger the need for pedigree information for each shipment, which they will get only with great effort or not at all.

Large manufacturers traditionally will not supply bulk drug ingredients directly to pharmacies. The sale of bulk chemicals to compounding pharmacists is typically a minuscule component of the typical authorized distributor's business. These manufacturers and wholesalers have no direct economic interest in ensuring that pharmacists continue to have access to bulk drug ingredients to compound medications.

Further, the final rule requirements will increase the administrative burden for larger manufacturers if

required to make separate documentation sufficient to confer authorized distributor status on a wholesale distributor. The increased administrative burden will raise the fixed costs for drug manufacturing, again, resulting in an increase in overall drug prices.

The inability of these distributors to purchase bulk drugs would risk the health of patients whose access to vital compounded medications would be seriously disrupted. Imposing pedigree requirements has been estimated to mean a loss of more than seventy percent of the bulk drug ingredients currently used in compounding. Taking into account the numerous areas in which drugs are routinely compounded, such as home healthcare centers and hospitals, this will affect 10,000 pharmacies. Tens of thousands of patients will not be able to obtain medical treatment necessary for quality healthcare.

Any benefits that could be gained through this rule would be substantially outweighed by the public health cost of preventing patients from receiving prescribed medications. FDA's final rule does nothing to advance Congress' objective of preventing the diversion or damage of drugs in the chain of distribution for finished form prescription drugs. In fact, FDA's final rule is inconsistent with Congress' intent on three points. First, Congress did not intend to include bulk drug ingredients.

Second, the impact of the final rule on small distributors of bulk drug ingredients will effectively destroy the practice of compounding, which is inconsistent with Congress' intent in passing the 1997 FDAMA. Third, FDA's interpretation of the pedigree requirements will create a redundant layer of regulation which will not increase competition, as intended by Congress. Instead, it gives more power to large manufacturers and will increase drug prices for consumers both at the pharmacy level through lack of supply and for the large manufacturers through increased paperwork and regulation. The final rule will have a devastating effect on pharmacy compounding, an effect which is entirely avoidable while still realizing the true intent of Congress.

The legislative history is clear that Congress intended only that PDMA prevent diversion in the chain of distribution of finished prescription drugs, not bulk drug ingredients. This is evidenced through the legislative history of the PDMA which expressly references only problems associated with the distribution of finished form prescription drugs and never mentions the diversion of bulk drug substances.

FDA's application of the pedigree requirements of the PDMA to bulk drug substances is contrary to Congress' expressed intent in passing PDMA. In addition, FDA's

burdensome requirements for the distributors of bulk drug ingredients are unnecessary. Sufficient quality control and anti-diversion safeguards and penalties exist under current FDA record-keeping, licensing and GMP regulations to ensure that damaged, adulterated or counterfeit bulk drug components are not processed into compounded medications for distribution to consumers.

FDA's application of these requirements to bulk drug ingredients is a significant and unwarranted departure from FDA and industry practice. The agency's interpretation of PDMA's pedigree requirement to apply to bulk ingredients is contrary to Congress' intent to apply the law to finished dosage form drugs. Most importantly, if the final rule is implemented as written, it will have a devastating effect on the patients who rely on compounded medications. The inability of pharmacists to compound drugs threatens the health of patients who require individualized therapies.

In closing, on behalf of IACP, I request that the FDA final rule be amended so that it is consistent with Congress intent to clearly indicate that the pedigree requirements apply only to distributors of finished form prescription drugs, not to the distribution of bulk drug ingredients. If FDA chooses to ignore the will of Congress, the rule should at least be consistent with industry practice over the past twelve years and allow an

unauthorized distributor to be demonstrated by two or more transactions with a manufacturer or authorized distributor during a twenty-four month period and require that any pedigree information required of unauthorized distributors only go back to the last authorized distributor. Thank you.

MS. AXELRAD: Thank you. I have some questions. I would like to hear a little bit more about how compounding pharmacies get their bulk drugs and what the distribution system looks like for them. I know there are some very large players in that arena, and I would like to know what role they play. Are they authorized distributors? Are they unauthorized distributors? What is their role, and how does the system work?

MS. CAPPS: I can tell you a little bit of information about that, but I can certainly supply you with a detailed explanation of the chain of command or the distribution channels. But, licensed repackagers of bulk ingredients for compounding procure chemicals or substances from the same sources that the manufacturers do, and these chemicals, if imported, are checked in customs and then they are sold to different distributors and wholesalers. I can give you more detail in writing, but when the repackagers receive these chemicals, these substances used for compounding, they are required through current Good

Manufacturing Practices to do identity testing on the substances that they receive.

MS. AXELRAD: When a drug is repackaged, does it indicate on it the source of the manufacturer?

MS. CAPPS: Every substance that goes to a compounding pharmacist is accompanied with a certificate of analysis.

MS. AXELRAD: And does that indicate who manufactured it originally or is that just a certificate of analysis prepared by the repackager?

MS. CAPPS: It is prepared by the repackager, and this is where I can give you more information because I really don't know, but the certificate of analysis tells the pharmacist what that chemical is and that it has been analyzed for identity. I believe the repackagers have to get C of A's from their source of supply, as required under FDAMA.

MS. AXELRAD: Well, it has to have a certificate of analysis. So.

MS. CAPPS: Right.

MS. OGRAM: So, is what you are saying that the primary test that is conducted is the identity test?

MS. CAPPS: I know that identity is required. I know that many of our suppliers and our members do more than that, but identity is required.

MS. OGRAM: So, if that were to be the primary test, a pharmacist would have no assurance of the potency of the substance or impurities that might be in the substance. An identity test would not go to that level.

MS. CAPPS: Well, again, I can supply you with information about exactly what our suppliers are doing, the information that they do provide to the pharmacists, but they do operate under Good Manufacturing Practices and are licensed by the FDA as repackagers.

MS. AXELRAD: We don't license repackagers. They may register as repackagers but we don't license any of those.

MS. CAPPS: Okay, then they are registered as repackagers, and I know they go through inspections by the FDA and have to provide information about the chemicals and the vendors that they deal with.

MS. AXELRAD: FDAMA also requires that any off-drug substance used in pharmacy compounding come from a registered establishment, which presumably means that somebody somewhere needs to know that originally it came from a registered manufacturer and, therefore, would have to know the manufacturer. How is that information conveyed down to the level of the compounding pharmacist?

MS. CAPPS: That it came from a registered establishment?

MS. AXELRAD: Yes.

MS. CAPPS: I don't know.

MS. AXELRAD: Can you find out and provide that for the record?

MS. CAPPS: Yes, I can. My main point is that this is an unreasonable interpretation. We have the FDAMA law. We are working through that, the implementation of the FDAMA law. Congress never intended for ingredients of finished dosage forms to be included in PDMA, and there has never been any discussion about it in the legislative history and there has never been any account of drug diversion or of problems with bulk drug substances.

MS. AXELRAD: Well, I think we have a disagreement on the legal interpretation of the statute so I think we need to get out on the table here as much as we can about the factual situation. You know, most of what you were saying seems to be consistent with what we heard from other speakers --

MS. CAPPS: Right.

MS. AXELRAD: -- that it affects any of the distributor chains for pharmaceuticals, setting aside the issue of whether it does or doesn't cover bulks, but if we were to decide that it did cover bulks then the problems associated with that would seem to be the same. But what I wanted to get at was whether there were any special concerns

on the part of the compounding industry that are different from the concerns that we heard expressed from the secondary wholesalers.

MS. CAPPS: And that is my point, there may be some other concerns but I think there are some other forums for dealing with that, specifically to compounding provision of FDAMA.

MS. AXELRAD: Well, are the licensed repackagers of the bulk ingredients -- they are the ones that buy direct from the manufacturers?

MS. CAPPS: No, they do not buy direct. They may. They may buy directly from the manufacturer but when we surveyed our suppliers that we work with, seventy percent of the chemicals that t hey do buy would come from secondary sources. So, they don't buy directly from the manufacturer.

MR. MCCONAGHA: When you say secondary sources, are you talking about secondary wholesalers?

MS. CAPPS: Wholesalers of raw ingredients, yes.

MS. AXELRAD: So, there is a whole secondary market of bulk ingredients, similar to the secondary wholesale market for finished pharmaceuticals?

MS. CAPPS: Right.

MR. MCCONAGHA: And, it is your experience that the majority of pharmacists are getting their bulk compounding products from these secondary players who would

not be authorized distributors under the new reg as it is written.

MS. CAPPS: The pharmacists purchase chemicals from repackagers. These repackagers get bulk ingredients and then they repackage them into smaller quantities that are more appropriate for the pharmacist to maintain in his pharmacy.

MR. MCCONAGHA: It is my sense and I may be wrong, so I welcome your thoughts on this, that many of the bulk chemicals used in compounding are actually foreign manufactured APIs that are imported into the United States versus drugs or bulk chemicals that are manufactured domestically.

MS. CAPPS: I don't know a percentage on that.

MR. MCCONAGHA: Do you have an idea? Are we talking about a majority?

MS. CAPPS: No.

MR. MCCONAGHA: Is it something that we could find out?

MS. CAPPS: Sure.

MR. MCCONAGHA: I would very much appreciate it.

MS. CAPPS: Yes, sure.

MS. AXELRAD: Just to sort of make sure I understand what you are saying in terms of these repackagers, is PCCA considered one of those?

MS. CAPPS: PCCA, Spectrum, Gallipod. In fact, we submitted comments on their behalf and there were six of them who signed those comments, and those have already been submitted.

MS. AXELRAD: Okay, and they buy from the secondary market.

MS. CAPPS: Or the manufacturer, yes.

MS. AXELRAD: And what percentage of the compounding industry do those six suppliers supply?

MS. CAPPS: That is a good question. We have determined that they probably supply like seventy-five percent of the compounding market. There are some others who are not represented in that letter that we are aware of. We do not work directly with them so we have estimated that.

MS. OGRAM: Do you know whether, generally speaking, pharmacists do any additional testing on the bulks that they receive from their suppliers?

MS. CAPPS: I do not. That is an issue that we have discussed in the FDA advisory committee meeting; in fact, I was just here for that in July -- should additional testing be done on finished dosage forms.

MS. OGRAM: And you mentioned that there were differences between the bulks and the finished products, and you said that there were sufficient anti-diversion safeguards and quality controls for bulks. Do you see them

as different from those that are in place for finished drugs and, if so, what are they?

MS. CAPPS: Well, first of all, for chemicals they have to go through customs so if they are counterfeit or if they are diverted, I would think there are safeguards in place -- is that what you are talking about? Chemicals?

MS. AXELRAD: Well, the trouble is that the restrictions in terms of what is let in through customs for a compounded product are far less than for an approved drug product because you can bring in a bulk substance, and if you say it is for pharmacy compounding then, you can do that without saying that it is an approved substance connected to an application or anything. So, in fact, there are far less controls on imported drugs, coming into the country for compounding, than for an approved finished dosage form.

MS. CAPPS: And that may be a concern but I don't think that this pedigree requirement would resolve that issue, and should it really be the responsibility of the repackagers to stop counterfeit drugs from coming into this country?

MS. AXELRAD: I would think that the compounding pharmacists would want the drugs that they are getting to be of high quality if they are going to be using them and then passing them on to consumers.

MS. CAPPS: Sure, and I would like to provide you

with the analysis and the information that the repackagers do provide or do conduct on the products. I am sorry, Ms. Ogram, did I answer your question at all?

MS. OGRAM: More or less. If you could provide any additional information though on the testing that the pharmacists might do, or the testing that the bulk repackers do and provide in the certificate of analysis, we would appreciate that.

MS. CAPPS: I will definitely do that.

MS. AXELRAD: Thank you.

MS. CAPPS: Thank you.

MS. AXELRAD: The next speaker is Paul Device, from Truxton Incorporated.

MR. DEVINE: Hi. Good afternoon. I would like to thank the FDA and the panel for allowing me to speak today, and Miss Henning, who I spoke with, who helped me arrange my appointment here.

I am from Truxton Incorporated, and we are a small distributor in the pharmaceutical field. We deal primarily with family physicians, and a lot of what applies here as far as the six questions that you have asked to be addressed has been addressed by some of the prior speakers. I wanted to talk about a few of the other points and just kind of reiterated them on a smaller scale.

In starting with question number six regarding a

relationship between a manufacturer and a distributor, as has been brought up earlier, from our experience, it is very difficult with certain pharmaceutical manufacturers to get a relationship with them where we are able to buy the merchandize from them, frequently because, as has been mentioned, many times we are just too small. And there are many companies, as has been enumerated -- 4,000 companies, similar to our company, throughout the country that operate and have this problem as well, and you can understand, you know, it might be difficult for certain pharmaceutical manufacturers to sell to 4,000 different companies.

In some particular instances we do have a direct relationship with a pharmaceutical manufacturer, however, the prices are skewed to the standpoint where, for example, it may cost us $30 per unit and other people or larger entities might be paying $24 or $25 a unit. So, in those particular instances, obviously, we are working at a disadvantage when we have to pay this escalated price and then see, obviously, to sell in another market.

As far as a written paper that would be necessitated between us and the pharmaceutical manufacturer, that puts us potentially at a disadvantage because, obviously, they can add things into the agreement over time. For instance, since we are smaller they may charge us more money to engage in a relationship with them.

Hypothetically, they may tack on a certain percentage based on our purchases, on our volumes. If we are only buying X amount of thousands of dollars of product from them over a month or a year, potentially we could have a fee for being able to deal with them. So, we are worried about that from the standpoint of is it going to open up a Pandora's box where the relationship between us and the pharmaceutical manufacturer could cost us more money which, of course, we would have to then pass on to the consumer and, in comparison to other entities in the marketplace, would just keep on increasing our cost beyond just paying a higher price.

This also leads to the potential down the road, I mean from the standpoint of some of the manufacturers that we have relationship with, I don't know what would all be involved in the contract that we would have to negotiate with them. Obviously, it could be some standard type of form that they may submit to us but from their end it also creates more paperwork; from our end it creates more paperwork. And, the potential of dealing with numerous pharmaceutical manufacturers now brings into our company, which is smaller, the necessity to review all of these documents and paperwork and send them back to them on a periodic basis.

As far as some of the other instances that have

been addressed, how does this come into play as far as the pricing? You know, there are certain products sometimes in the marketplace that have an importance and a necessity, and very often these are the particular types of products that have differences in the price discrepancies between maybe our company and another company. So, it is important for us to be very competitive with those prices to our customers because, if we are not, we are going to lose their business and very often losing just a handful of items on the top can ripple down and trickle down to all the products that the customer would purchase from us. Some of the larger companies, obviously, are aware of this and, of course, they are going to use this to their advantage.

As I mentioned, our company and many companies like our company throughout the country are big players or helpful players in the physician office setting and we are all familiar, of course, with the family doctor. And, we are able, as a smaller company, to provide quick and efficient service to the family physician at a reasonable cost because we, obviously, cannot be excessive in our pricing or we are going to lose that particular physician as a customer. Conversely, the larger companies cannot, obviously, charge a tremendous markup to the physician because he or she has companies like us to fall back on if that is the case.

As has been mentioned earlier, we also act as an arbiter because we make sure that the family physician or the doctor that we are dealing with is able to get the product quickly and efficiently, many times the next day, and because we also operate regionally we can frequently provide the product, if need be in certain cases to a physician the same day and, obviously, this is an advantageous position for the doctor in an emergency type of situation. We don't do that constantly throughout the business day but we are able and do it sometimes daily.

So, from this standpoint for what the implications can be with this ruling, as a small company we view this as something that is imbalanced for us, and has the potential not only for us but for other companies -- and, by the way, I am very disappointed that there aren't more companies here. Some of the people that I did speak to this week in discussion of this meeting told me that they did not want to come basically out of fear, out of fear of the relationship with the pharmaceutical manufacturers feeling that, you know, their presence here could possibly damage their relationships with the pharmaceutical companies either today or down the road.

Thank you for the opportunity to speak here today.

MS. AXELRAD: Thank you. Questions?

MS. O'ROURKE: Are you trying to get a feel for

the pedigree issue? Clarify your position on this for me. Do you feel that the pedigree issue should be done away with or should it become universal?

MR. DEVINE: Well, I think that the fear, again, that we have there is that in instances, hypothetically, where we cannot get a product directly from a pharmaceutical manufacturer -- again, that might be because the we don't have the volume to warrant purchasing merchandize from a pharmaceutical manufacturer. Now, there are times where we do have the volume in comparison to other companies that are in the field, but it has already been mentioned that sometimes the pharmaceutical manufacturer feels they have enough representatives so they don't want to take on new distributors. But if we are not able to get it directly from a distributor and we have to get it from another source, now we are dependent upon that other source to give us all the necessary information that we need to comply with the PDMA law. Now, many times for some of these outfits, especially some of the five largest wholesalers, the requirements that I feel they would have to meet, when you are talking about entities that are dealing with thousands of products and thousands of pieces of merchandize -- they may just elect not to give us that type of information, or if they do they may say, okay, well, we are going to provide that information to you but it is going to be at an

increased cost, which has the potential to push us out of the market because our cost is just too high and then, in turn, we would have to pass that on to the consumer which would be a disadvantage to the consumer as well.

MS. AXELRAD: Are they using bar codes at all in the industry? I think for inventory control and things like that some people use bar codes already. It seems to me that if the industry used bar codes that you could just incorporate a few extra pieces of information into that coding and then everybody who handled the pharmaceutical down the line would be able to scan it and print it out. Would that relieve the burden perhaps of this, if a bar code were put on at the manufacturer and then wherever it went along the line everybody could trace it somehow?

MR. DEVINE: Well, we are a smaller company so we don't we deal with bar codes. I am not sure of all the machinations that are necessary to handle that, but from our standpoint, I think, again, it would just be prohibitive with many products for us to do that on a regular basis. So, I don't really think that would be a tremendous advantage to us.

MS. O'ROURKE: Are you familiar with the licensing wholesaler regulations in terms of storage and record-keeping?

MR. DEVINE: Oh, yes, we are regulated by the FDA.

In fact, we get inspected by FDA. We are licensed by our state. So, we have all the compliances, you know, with the FDA.

MS. O'ROURKE: Do you feel that those are satisfactory and there is no need for a pedigree?

MR. DEVINE: Yes, they come in and they check out our establishment and, you know, they do it on a regular basis, and we have a relationship with them and it is an ongoing relationship. I don't know if I mentioned this earlier, our company has been in business since 1957 and throughout that period of time we have been regulated and monitored by the FDA.

MS. O'ROURKE: Thank you.

MR. RAY: Paul, what percentage of your business would you say involves buying from authorized distributors who refuse to provide a pedigree or the information?

MR. DEVINE: I think it can be anywhere from maybe twenty-five to thirty percent. At times it may be higher than that. There are certain companies that we are authorized to buy from but, as I mentioned earlier, the pricing that they charge us would be prohibitive for us to sell that product in the marketplace and we may go to another source who is getting it for less. Many times the price they charge us is not a substantial increase over their cost so then we will, in turn, sell that at a discount

to the customer. Thus, we are able to help them by keeping their cost lower and many times the price that we are charging them is a marketplace price. So, even though it is costing us more than some other competitors in the marketplace, we have to monitor our pricing so that it is an advantage to the customer and to us as well.

MR. RAY: The physicians that you supply, are they buying all of their drugs through you or people like you, or do they buy also from some of the major ones?

MR. DEVINE: This is just an estimate on my part, but I would say that ninety to ninety-five percent of the customers that we have deal from other sources, other than ourselves, and they do that for a variety of reasons -- for pricing and availability. Pricing is a big factor in their decision. And, if I were in their shoes I would want to have another source as well rather than just relying upon one company all the time, in case there is a problem with availability.

MR. RAY: Is it your sense that there are other small distributors like yourselves? In other words, if you couldn't survive in this market, would the major wholesalers kind of step in and fill that gap?

MR. DEVINE: Well, if we are talking about the five major pharmaceutical wholesalers, no. I can't see any way that they could fill that role because it is too small

of a market for, you know, what they are used to dealing with. It is night and day, the differences between some of these volumes as far as what a large national wholesaler is used to dealing with versus a small distributor like ourselves. There are even smaller national wholesalers who would not be able to fill this marketplace just because it is not a big enough volume for them to get into the marketplace.

MR. TAYLOR: So, for smaller scale entities like yourself, it is not so much that they are unwilling, it is just that because of the economic factors there is not the same incentive to fill those smaller -- well, to sell to some of the smaller accounts --

MR. DEVINE: You mean from the pharmaceutical manufacturers?

MR. TAYLOR: Right.

MR. DEVINE: Yes, and I understand that, you know, to a certain degree from some of their perspectives, that if we are not able to give them a tremendous volume then, you know, it is not to their advantage and might not even be to our advantage to purchase from them. But, as I mentioned, there are certain instances where we do have volumes to warrant dealing with a pharmaceutical manufacturer directly but, as it has been pointed out already here today, they don't return your calls or reply.

MR. TAYLOR: You sort of answered my next question because I was going to ask what might be some of the reasons for the refusals, but you just stated that reasons aren't given because often there may not be a real reply at all.

MR. DEVINE: Yes. Yes, there is no reply or, as has been mentioned here already, they feel like they have enough distributors in the marketplace already to satisfy the need for their distribution. I think sometimes that may be the case; I think many times it is not the case. They are trying to control who they sell to and how their product is handled.

MR. TAYLOR: Fair enough.

MR. RAY: Have you had the same experience in terms of dealing with them on a regular basis while they refuse to provide you with an authorized?

MR. DEVINE: Yes. There was a gentleman just this week at my office that was telling me that there is a company we are trying to set up with, and he has called them over a period of months ten to fifteen times, and we just don't get a reply, -- no, there is not even an answer from the standpoint of saying, no, we have enough distributors. And, many times when we are making these calls, we make these calls also occasionally to companies that we have a relationship with but we are trying to get into that tier of price discounts, and with some products in the industry

there are just one or two companies that have that bottom line price and everybody else is paying a higher price throughout the industry.

MR. RAY: You mentioned I think that you deal sometimes now with secondary wholesalers. So you actually receive pedigrees, I take it, from time to time.

MR. DEVINE: Yes.

MR. RAY: I am really just curious here, when you get those pedigrees, do you put much stock in it? Is it your sense that, oh, this is just a stupid government requirement? Or, is there a sense that, hey, this pedigree actually gives me some meaningful assurance in terms of the quality of the product I am receiving?

MR. DEVINE: I would say with probably ninety percent of the companies that we deal with, these are businesses and pharmaceutical companies, distributors and manufacturers that have been in the business for many, many years. So, when we get something from those entities, no, we are not really concerned about the quality of the products because we know these are quality companies that are dealing with quality products all the time. These are established companies that have been in the business for a long time and many of them are well-known throughout the industry.

MR. RAY: Thank you.

MS. AXELRAD: What do you do with the pedigree when you get it?

MR. DEVINE: Generally it is going to be attached to the invoice that the merchandize comes in with, and so it will be included with that. You had mentioned earlier about the FDA system that is in place right now. I can't really say if it has happened every time but I would probably say that, yes, there are products in our company that are checked and we are asked to pull out invoices for products, you know, verifying the tracking of that product, who we got it from, the date, etc., and that is pretty routine, when we do have an inspection, that someone requests that someone requests that information.

MS. AXELRAD: Is that an FDA inspection?

MR. DEVINE: Yes.

MS. O'ROURKE: If a customer wanted to know the source of a product that you sold to them, are you willing, or have you found that your suppliers are willing to give you that information from their own records, or is there any problem with that?

MR. DEVINE: If we had to reveal that information to certain entities, we would go out of business. I don't mean to sound exaggerating but it is that truthful; we would go out of business.

MS. AXELRAD: Why?

MS. O'ROURKE: Is it a competitive issue?

MR. DEVINE: Yes. They will be able to go directly from that other source. Many times they know of that company. You know, the marketplace is aware. It is the same thing under this scenario, you see all these large hardware companies opening up and, let's say, I own a small hardware store on the corner and I want to go to a Home Depot and pick up certain products there because I can't get them directly from the manufacturer in that hardware business, well, if I had to tell every customer that walked into my store that, you know, I went over and got this at Home Depot and they got it for ten percent less than me -- and many times, as I mentioned earlier, it is not even that they can get it for less at the other facility, I mean I am going to probably mark it up and be equal in this scenario with the Home Depot, but it is just the fact that you are telling them this is where I got it from. This person is also in the marketplace. You know this person. Why don't you go over there and see what their price is. Again, if I was on the other end of this transaction, that is what I would do. Look, they are buying it from this other company; let me find out what their price is.

MS. O'ROURKE: Do you know if that is true all the way up the line all the way to the manufacturing level or the authorized distributor level?

MR. DEVINE: I don't think it is true all the way up the line, no. I mean, there are certain times where if that were to happen up the line, you know, they may call another source and find out that that price would be the same as what we are offering it at but in certain instances, yes, it would have an impact as well.

MS. AXELRAD: How do these things work? I mean, operationally work. Do you put out a price list that says, okay, I am offering this product? And, if you do, doesn't everybody know that you are offering it? Is it on a computer? Do people bid on these things? I mean, how does this mechanically work?

MR. DEVINE: As far as us selling to the physician market?

MS. AXELRAD: Well, in terms of the products that you buy, with you out there in the market saying I want this antibiotic, or something, and you want to find out where you can get it at the cheapest price, don't you call around all the logical sources to find out where the cheapest price is and get it? Why can't anybody do that? You say there is a big competitive thing by disclosing to people who you got it from and I am trying to figure out how the thing actually works and if that would be news to anybody.

MR. DEVINE: Well, with different product categories or different products there are different

marketing strategies. With some products, some of the large distributors and wholesalers throughout the country -- they kind of have two divisions. They will have a division that sells to a physician in this particular case, and then therapy will have a division that sells to our company. For instance, if you are talking oral antibiotics, let's just say, it gets back again to the pricing strategy. There are companies who will market to our type of business and they will buy it at a low price from the pharmaceutical manufacturer and then try to market it to companies like ourself. So, a lot of it is done through the mail; a lot of it is done through the phone as well. And, many times these pricing advantages are pretty standard. So, we know where to go to on a regular basis when we need a particular product or which areas to look at for the pricing for those particular items that we might be interested in. There is some fluctuation on products and companies but, for the most part it is probably fairly standard for us.

MS. O'ROURKE: Are you saying that normally once relationships are established with various suppliers for you, you might check or canvass all of them for the price of a certain item, but basically will not go outside that circle of established contacts because you know who they are and you have a good relationship with them? Or, basically you will check anyplace?

MR. DEVINE: Well, many times there is not the ability to check every place because, as I mentioned, if we are looking to buy just strictly on price then there are only one or two companies, many times, that have the best price, and the reason why they have that best price is because they have been set up with the pharmaceutical manufacturer to receive that best price. So, if somebody does have a best price, it is generally not -- I mean, off the top of my head, I wouldn't say it is larger than five companies in the industry that are going to have that low price.

MS. O'ROURKE: So, it is already channeled at the top.

MR. DEVINE: Yes, it is already skewed to certain companies at the top.

MS. AXELRAD: Wouldn't everybody know that?

MR. DEVINE: Yes, the people in our distribution market know that, but the end users, many times, are not aware of this or they don't have access to that price and that product from that particular company.

MS. AXELRAD: So, the end user is the pharmacy?

MR. DEVINE: Yes, we do deal with some pharmacies but we also deal with physicians too.

MS. AXELRAD: Okay.

MR. DEVINE: A lot of those larger entities that

we are buying it from, they don't want to deal with the physician market. We might buy 1,000, 5,000, 10,000 pieces and you might have a physician who only wants to buy 5, 10, 20 pieces. It is just a whole other system of operating a business to deal in that marketplace versus dealing in the larger volume marketplace.

MS. AXELRAD: Do you ever deal with compounding pharmacies?

MR. DEVINE: No, we do not. No, we are not involved with that. I am not real familiar with that field but I would venture to say it is a whole other market strategy.

MR. TAYLOR: Paul, you noted earlier that I guess attendance by others who are in your similar position was affected because of their fear of, I guess, manufacturers. If you could somehow encourage them, if they do have additional input, to submit it to the docket, I think that would be useful.

MR. DEVINE: Yes, we have talked about trying -- there are certain manufacturers reps -- this kind of gets back to what you were saying abut how do we find out about a product -- there are certain manufacturer rep salespeople who have contact with multiple companies, and if there is a product that is available at a competitive price they will contact us. So, they have knowledge of other distributors.

We are also talking about sending out faxes and documents. I know that some people have done that in the past. I think Tony Young has mentioned that he has been involved in that. In certain instances, and I don't want to speak for someone else but I don't know if they really understand the full implication of, you know, what this involves and I believe potentially how harmful it could be for their business. But, yes, there is a need probably for those of us, like myself that are following this and trying to follow it, to try to make others aware as well.

MR. TAYLOR: And to educate us. Obviously, submitting information to us just helps us better understand your perspective.

MR. RAY: Yes, even if they were afraid to come here, they can send in a comment --

MR. DEVINE: Send in a letter in writing.

MR. TAYLOR: Even if they didn't feel comfortable coming in here, like you did, and answering questions and sort of being out in the spot light, they can still submit documents to the docket and we would still give them the same consideration.

MS. AXELRAD: Or they could put some together and have somebody submit them for them.

MR. DEVINE: Yes, as a group.

MR. O'ROURKE: The equivalent of a brown paper

envelope.

[Laughter]

MS. AXELRAD: Well, it would be nice to have somebody who would be willing to say I am acting on behalf of the following six people.

Anybody else? No? Thank you very much.

MR. DEVINE: Thank you.

MS. AXELRAD: Now we are going to turn to blood issues. Our next speaker is Chris Lamb, representing the American Red Cross.

MR. LAMB: Good afternoon. My name is Chris Lamb, and I am pleased to be here today on behalf of the American Red Cross, where I am the chief operating officer for plasma services.

I would like to thank the Food and Drug Administration for delaying the implementation of certain provisions of the Prescription Drug Marketing Act, the PDMA, to allow affected parties to provide information on the consequences of PDMA on the public health and the delivery of critical life-saving plasma products.

I am followed today by Dr. Celso Bianco, with the American Blood Center, and Laura McDonald, from Blood Centers of American, and together we represent the volunteer whole blood collecting organizations in the United States, and you might want to listen to all three of us and then we

could take questions together.

It is important to note that Congress enacted PDMA to preclude hospitals and other healthcare entities from obtaining pharmaceuticals at discounted prices and then reselling these drugs at profit. According to the legislative history, this practice was considered to be unfair to wholesale and retail prescription drug distributors who had to pay average wholesale prices. Congress also intended to prevent the sale of outdated and other unsafe and ineffective drugs through the diversion market.

These are laudable goals, and the American Red Cross supports efforts to ensure public health is not compromised by adulterated drugs and biologics. The American Red Cross is concerned, however, that the final rule inappropriately includes plasma derivatives in the procedures and requirements of PDMA. We believe this runs counter to the intent of Congress, when it passed PDMA, and FDA's own intentions to exclude blood and blood components from PDMA's conditions.

We believe that the most rational way to rectify this oversight is to exclude blood banks from the definition of healthcare entity. This would keep in place the protections found within PDMA to ameliorate problems that the Act was intended to fix, at the same time, excluding

blood banks from PDMA's definition of a healthcare entity would allow for the continued distribution of blood products and plasma derivatives in its current manner so as to ensure the most efficient distribution of these life-saving products. Alternatively, we suggest that the FDA expand the exclusion for blood or blood components to include plasma derivatives.

Today, I will outline several reasons why blood banks should be excluded from the definition of healthcare entity and why plasma derivatives should not be part of PDMA's requirements.

These are, one, the current exclusion of blood and blood components from the provisions of PDMA; two, congressional intent and statutory language arguing for the exclusion of blood banks from the definition of healthcare entity; and, three, supply and public health concerns.

I will also answer the questions posed by FDA in the public hearing announcement regarding the distribution of plasma derivatives. The American Red Cross is an independent, not-for-profit corporation and the largest provider of blood services in the United States. The American Red Cross collects and distributes about one million liters of plasma and plasma derivatives, accounting for about ten percent of the nation's supply of plasma derivatives. We contract with companies like Baxter Health

Care and Vitech Corporation and the Swiss Red Cross to manufacture anti-hemophilic factor to treat hemophilia A, intravenous immune globulin to treat various immune disorders, albumin and solvent detergent-treated plasma for transfusion products under the FDA licenses of those companies. These plasma products are distributed under the American Red Cross label to hospitals, hemophilia treatment centers and other providers.

In regard to the exclusion of blood products, the final rule stated that FDA had made a final determination that blood and blood components intended for transfusion should be excluded from all of the restrictions and requirements of PDMA. These products included whole blood, red blood cells, plasma, fresh-frozen plasma, cryoprecipitated anti-hemophilic factor and platelets. We concur with FDA's determination with the rationale to exclude these products. In their determination, FDA noted that because application of PDMA to blood and blood components would produce possible shortages, the agency believed that Congress could not have intended to subject blood and blood components to PDMA's provisions. We believe this reasoning is valid and appropriate.

We would also point out that such reasoning also applies to plasma derivatives distributed by blood banks, as evidenced by recent events surrounding shortages of some

plasma derivatives including immune globulins.

In regard to congressional intent, the PDMA notes that the term "entity" does not include a wholesale distributor or drugs or a retail pharmacy licensed under state law. This language would appear to be unambiguously confirmed, that an exception to the PDMA's sales restriction exists for wholesale drug distributors and retail pharmacies licensed under state law. The definition of a healthcare entity in the final rule runs counter to this congressional intent by effectively precluding healthcare entities from obtaining state licensure to distribute drugs. Implementation of this definition is contrary to the intent of Congress and would contradict the clear and unambiguous language of PDMA, which is prohibited by law.

Given that there has never been any indication of any distribution abuses of this type, banned in the PDMA, with respect to any licensed blood products or plasma derivatives, it would appear that FDA's own interpretation of the clause prohibiting anyone from simultaneously being a healthcare entity and distributor would not apply to blood banks acting as legitimate licensed wholesalers.

Neither prior to nor during the extensive congressional investigations relating to PDMA were there any documented abuses that would suggest that Congress intended that blood centers be prohibited from simultaneously acting

as healthcare entities and wholesale distributors. Furthermore, in a letter to the FDA, dated May 27, 1994, Congressman John Dingell, then Chairman of the Commerce Committee, noted that many full-service blood banks often serve as distributors of blood products and presumably comply with FDA regulations by registering with their respective states as wholesalers. He pointed out that FDA's proposed prohibition on a person simultaneously being a healthcare entity and a retail pharmacy or a wholesale distributor suggested that such full-service blood banks that have registered with their respective states as a wholesaler would be prohibited from either providing blood components or plasma derivatives as part of their services. He noted that the subcommittee understood that the FDA intended to address this issue in order to avoid disrupting the supply of biologics, sold as prescription drugs, to individuals with hemophilia and those with compromised autoimmune systems.

The Red Cross believes that the FDA has not completely addressed this issue since the agency has made no changes from the proposed rule to the final rule that would exclude blood banks from the restrictions outlined in the final rule, or allow blood banks to serve as distributors of blood products and plasma derivatives.

In regard to the public health consequence of not

allowing blood banks to distribute plasma derivatives, the final rule implementing PDMA suggested that the distribution of plasma derivatives would not be harmed by excluding blood centers from distributing such products. In fact, the American Red Cross collects over one million liters of plasma annually. About eighty-five percent of our anti-hemophilic factor is provided directly to homecare companies, hospitals hemophilia treatment centers, public health service facilities and other healthcare organizations. Implementation of the final rule, as it is presently articulated, would deny hemophilia patients access to this life-saving and life-enhancing product since many of the treatment centers are smaller entities that are not usually supported by large distributors.

Additionally, approximately fifteen percent of our IGIV products and ten percent of our albumin product are provided directly to healthcare providers. Disruption in the supply chain of these latter two products could result in patient access issues as the products directly provided by the Red Cross to healthcare organizations account for about 26,000 to 69,000 infusions annually. Clearly, the congressional intent to exclude blood products from PDMA because of potential interference with the nation's blood supply should also be extended to potential disruptions with the nation's plasma derivatives supply.

In regard to FDA's questions outlined in the announcement for this public hearing, the Red Cross cannot speak to the distribution systems of other prescription drugs. We distribute our plasma derivatives from our warehouse operated by a contracted firm. Products are distributed under the Red Cross label. Other distributors and non-distributors such as hemophilia treatment centers contact the warehouses needed to request delivery of our products.

As I mentioned above, this arrangement is advantageous to small or medium size hospitals that have little need for inventory and no ability to negotiate with larger distributors. The effect of the PDMA final rule, as published, would have a dramatic impact on the distribution of our plasma derivatives and would jeopardize the health of the patients we serve.

Obviously, the supply of many of these products is tenuous at best. Recent reports by the U.S. General Accounting Office, several congressional hearings and discussions at HHS and FDA advisory committee meetings have all highlighted intermittent supply problems affecting such products as IGIV, intravenous immune globulin. Disrupting the distribution chain by prohibiting blood banks from distributing plasma derivatives would only exacerbate an already precarious situation.

As noted previously, this is the very reason given by FDA to exclude blood and blood products from PDMA. The agency believed that such an exclusion would seriously impede the present blood distribution system and, thereby, substantially interfere with and reduce the nation's blood supply. To disrupt an already inelastic supply of these life-saving plasma products can only result in problems for patients attempting to obtain these products.

Patient safety may also be jeopardized since systems for handling product retrievals and recalls will be further complicated in order to take into account this additional step in the distribution chain. Importantly, retrievals and recalls could be delayed as the administration burden to track these products becomes more complicated.

There are also economic costs resulting from the implementation of the final rule. Increased prices are almost inevitable since the current markup of plasma derivatives products by distributors is approximately six percent over and above the price provided by the supplier. It is also known that these markups can be significantly higher during product shortages.

FDA has also asked whether or not there would be an increased risk of distribution of expired, adulterated or otherwise unsuitable plasma derivatives. We believe this

outcome is highly unlikely. These products are the result of a very complicated collection and fractionation or manufacturing system which cannot be duplicated or expanded without substantial capital investment.

Given the basic inelasticity of supply for many of these products due to the rather nature of the plasma itself, it is dubious whether these products can be obtained through a diversion market, or be adulterated or otherwise made unsuitable for human use.

Lastly, FDA asked whether manufacturers of plasma products provided these products to charitable organizations at a lower price when compared to other consumers. The Red Cross does not provide products to charitable organizations at different prices than other customers. All hospitals basically receive the same price. We also do not maintain oversight of pricing and distribution practices once the product is no longer under our ownership. Thus, we have no explicit understanding that our plasma products will be resold to other healthcare entities, distributors or retail pharmacies.

In conclusion, the American Red Cross requests that blood banks be excluded from the definition of healthcare entity. This we allow blood banks to continue to provide life-saving products and ensure an adequate national supply of blood components and plasma derivatives. The

current exclusion of blood components from t he provisions of PDMA highlight both congressional and FDA concern about maintaining an adequate blood supply. Clearly, such concern is also warranted in the plasma derivative arena.

Alternatively, the Red Cross urges FDA to exclude plasma derivatives from PDMA. This will provide for the enforcement of the PDMA provisions in accordance with congressional intent, while still maintaining an essential component of our healthcare system.

Again, the American Red Cross appreciates the opportunity to comment on this very important issue to our organizations and the patients we serve. Again, I am happy to answer any questions, or if you would like to hear from the other two organizations first.

MS. AXELRAD: Why don't we hear from all of the organizations, as you have requested, and then we will address questions to you all collectively.

DR. BIANCO: Thank you. I am Dr. Celso Bianco. I am the Executive Vice President for America's Blood Centers. Unfortunately, Jim MacPherson was unable to attend; he wasn't feeling well today, but I feel very comfortable being here and I thank you for that opportunity because until two weeks ago I was the vice president for medical affairs of the New York Blood Center, and I was actually in charge of our program of support of three hemophilia treatment

centers.

ABC is the national association of not-for-profit regional and community blood centers that are responsible for providing nearly half of the nation's volunteer donor blood supply. Founded in 1962, ABC, through its members, is committed to ensuring the optimal supply of blood, blood components and blood derivatives, and to fostering the development of a comprehensive range of the highest quality blood services in communities nationwide.

ABC has been an active participant in FDA's Prescription Drug Marketing Act of 1987, PDMA, rule-making process, and welcomes this opportunity to again address the status of blood centers under the final rule.

In our statement today we will address the specific questions posed by the agency in the Federal Register notice announcing this hearing that pertain to the distribution of blood derivatives by blood centers and other healthcare entities.

The first question was what distribution systems are available for blood-derived products? Do these distribution systems differ from those for other types of prescription drugs and, if so, how?

Over fifteen percent of all U.S. plasma derivatives are distributed to hospitals and hemophilia treatment centers by community and Red Cross blood centers.

In most instances these supply relationships date back thirty to fifty years. Originally these relationships arose because blood centers provided plasma. As pharmaceutical-based blood derivatives began replacing plasma for transfusion, some blood centers and hospitals allowed these derivatives to go into the hospital pharmacy to be distributed like drugs. But many hospitals and hemophilia treatment centers wanted blood centers to maintain their role as neutral and community-based providers for all blood products, whether these products be for transfusion or other therapeutic use by patients. Consequently, hospitals came to rely on the expertise of many blood centers in fulfilling the majority of their blood product needs, as laboratory service and expert medical consultative needs for all licensed blood and plasma products, including albumin, immunoglobulin and anti-hemophilic factor.

Of critical value to hospitals is that the blood center as a neutral, not-for-profit entity is able to distribute products in short supply equitably throughout the community it serves, preventing hoarding or products by hospitals; preventing gouging in times of shortages; and providing for the smooth transfer of products as needed between hospitals. This role has been specially valuable over the recent past given the critical shortages of immunoglobulin and alpha-1 antitrypsin.

It is also important to emphasize that community blood centers have a recall, tracking and distribution system for their blood components and blood derivatives. These are services that many hospitals find to be of great value and that manufacturers of derivatives or commercial distributors do not offer. I must say that actually the difference between blood centers and pharmaceuticals in the way that we handle products is that each of the units of blood that we collect is one lot of product. American's Blood Centers has 6.5 million lots of products that we process every year, and we have cradle to grave tracking of those products.

The second question was what effect would the PDMA final rule, as published, have on the distribution system for blood-derived products? What, if any, adverse public health consequences would result? What would be the economic cost to manufacturers, distributors and consumers of blood-derived products?

The blood center hospital relationships that I outlined in response to the first question have been successful and play a crucial role in scores of communities across America. If the regulations implementing FDAMA stand as written, these time-honored relationships would be replaced by untried mechanisms of derivative distribution. For instance, regulations would prohibit a twenty-plus year

arrangement between the New York Blood Center and three federally funded hemophilia treatment centers which provide products to patients in an efficient and cost-effective way. Through this arrangement, the New York Blood Center support services deliver the products to the patients' homes and pick up and dispose of biological waste, such as contaminated infusion sets and vials. The patients are extremely happy with these services, and the physicians are pleased we this solid support.

Similarly, a hemophilia treatment center program begun by Puget Sound Blood Center in 1974 provides care for some 900 patients with congenital bleeding disorders in Washington, northern Idaho and Montana. Access to effective treatment for these patients would be similarly disrupted if the regulations prohibit blood centers from distributing these products. No purpose is served by preventing blood centers, that already provide blood and components for use by patients, from distributing critical care products to the same patients.

Regarding the direct healthcare entity role of blood centers, which is the reason they would be prohibited from distributing blood derivatives under PDMA implementation of regulations, most blood centers provide a very limited amount. That is, less than five percent of all activity of direct healthcare. However, these services are

critical to public health in that they provide patients access to higher levels of expertise than would be possible to obtain, or practical to maintain at individual community hospitals.

Examples of healthcare services provided by blood centers include therapeutic phlebotomy, plasma exchange and stem cell and cord blood collection and processing. By providing for such services though a centralized blood center, the medical expertise of the blood center can be leveraged in a manner that ensures community-wide access to the highest quality blood services available.

ABC is also concerned that forcing blood centers to choose between acting as a healthcare entity or a wholesale distributor will have a negative economic impact on the provision of blood services and products. The healthcare services currently provided by blood centers are critical to efforts to contain health costs in that they eliminate the need to duplicate such services at multiple locations. In order for hospitals to extend the same level of medical expertise with respect to blood-related healthcare services as currently provided by blood centers, significant additional expenditures would be required to attract and retain qualified medical personnel. This, in turn, would raise the price of these services and blood products to consumers.

The current system represents a much more dost-efficient approach than will be dictated by the final rule. Last year, for instance, the Puget Sound Blood Center's participation in the hemophilia treatment center program saved patients and third-party payers, including Medicaid and Medicare, 7.6 million dollars.

Economic costs associated with distribution of blood-related products will also be negatively impacted if blood centers are not able to act both as healthcare entities and wholesale distributors. Rather than being able to rely on the current centralized distribution systems, hospitals will have to maintain their own inventories incurred in the attendant costs. Moreover, during periods of shortage or blood-related products hoarding by individual hospitals is almost certain to occur. Such practices result in artificially inflated prices and will likely leave some hospitals without the necessary product. In contrast, the current distribution system in many communities around the U.S. ensures that product distribution is achieved in a fair and efficient manner, and provides an objective mechanism for redistribution on an as needed basis during times of shortage.

The third question was if blood-derived products were excluded from the sales restrictions, that is, if such products were permitted to be sold by healthcare entities,

would there be an increased risk of distribution of counterfeit, expired, adulterated, misbranded or otherwise unsuitable blood-derived products to consumer and patient? Why or why not?

We cannot address this issue for all healthcare entities, only for community blood centers. There is no evidence that the current system of derivatives distribution by blood centers results in any distribution of counterfeit, expired, adulterated, misbranded or otherwise unsuitable blood-derived products to consumer and patients. The legislative history behind PDMA supports this. Indeed, the lead congressional champion, Congressman John Dingell, told FDA that Congress never intended to prohibit blood centers from distributing blood derivatives. In addition, blood centers that purchase and distribute blood-derived products, since the early '90's complied with the state licensing requirements by obtaining state wholesale distributor licenses. Thus, they are already complying with the safety tenets of PDMA.

The healthcare functions performed by blood centers are carried out under supervision of medical experts in conjunction with the hospital's and/or patient's own physician. Importantly, since all FDA licensed blood centers must comply with FDA's Good Manufacturing Practices for the majority of these functions, these healthcare

functions are carried out in a GMP compliant environment and all blood centers, as you know, are licensed establishments -- all that are operating legally at least are licensed blood establishments.

The value of this specialized medical expertise that exists in blood centers is critical to community healthcare and the ability of the blood center to provide this medical expertise is subsidized by the small margins they earn on the sales of plasma products. Such specialized medical expertise, by and large, does not exist in the majority of local hospitals. Rather than promulgate a rule that weakens the blood centers' ability to carry out these functions, FDA should be promulgating rules that encourage safer, more medically appropriate and evidence-based uses of blood, blood components and blood derivatives.

If the final rule prohibits community blood centers from simultaneously providing healthcare services and distributing blood-derived drugs, we believe there actually could be increased risk to patients who rely on the current relationships between blood centers and hospitals for the life-saving drugs they receive.

The fourth question, and final question, do manufacturers of blood-derived products provide these products to healthcare entities, particularly those that are also charitable organizations, at a lower price when

compared to other customers? Do manufacturers sell these products to charitable or for-profit healthcare entities with the understanding that the products will be used for patients or the purchasing healthcare entity and will not be resold to other healthcare entities, distributors or retail pharmacies?

To the extent blood centers provide blood-derived products to hospitals at lower prices when compared to other vendors, it has nothing to do with the fact that the centers are charitable organizations or healthcare entities. It has solely to do with their abilities to leverage economies of scale on behalf of many of the hospitals they serve. Thus, blood centers are not unfairly competing with other distributors of these products, nor are manufacturers granting centers special pricing that would not be available to similarly situated distributors.

More importantly, the statutory language of section 503(c)(3) of the PDMA, which states that the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law, establishes that entities may simultaneously fulfill these roles. Congress did not intend that these exemptions from resale restrictions would create a loophole for entities participating in any form of prescription drug diversion. Instead, we believe that section 503(c)(3) mandates a

regulatory scheme be devised whereby a healthcare entity can operate as a wholesaler distributor or a retail pharmacy within lawful parameters.

In summary, and as described above, there are multiple advantages to patients, to hospitals and to blood centers resulting from the current distribution and shared service arrangements between hospitals and their community blood centers. These benefits will be lost if blood centers are denied the ability to act as both healthcare entities and wholesaler distributors. No downside or adverse effect has been shown from these arrangements. Indeed, adverse effects would result if FDA's final rule were implemented and community blood centers could not simultaneously provide vital medical services and consultation, and distribute blood-derived drugs. If FDA forces blood centers to make such a choice, what will they do? Where would the least harm occur? ABC urges FDA to revise the final rule to allow the dual functions of community blood centers so they may meet the important public health needs of the communities they serve. Thank you very much.

MS. AXELRAD: Thank you.

MS. MCDONALD: My name is Laura McDonald, and I thank you for allowing me to speak to you today on behalf of Blood Centers of America, its subsidiary hemarica and the thirty blood collection organizations in the United States

that we represent.

These organizations produce 525,000 liters of recovered plasma annually, from which almost 20 million grams of therapeutic proteins are derived. Many of these blood collection organizations also distribute the blood derivatives that are manufactured from the plasma.

The purpose of my statement today is to make certain points about the final rule as they relate directly to the services provided by community blood centers and the negative impact this act might have on both the provision of these services and the healthcare entities served. Like the American Red Cross and America's Blood Centers, we are in agreement that enactment of the PDMA has laudable goals to protect the public against the threat of subpotent, adulterated, counterfeit and misbranded drugs resulting from drug diversion schemes or drug diversion submarkets, and that the protection of the public can be accomplished by prohibiting commerce of any prescription drug that was purchased by a public or private hospital or any other healthcare entity.

However, blood centers fall under the edge of the PDMA's definition of a healthcare entity to the extent that some centers provide minimal services directly to patients, which may include certain diagnostic or therapeutic services. We believe blood centers should be excluded from